TaiDoc TaiDoc Technology Corp.
A Good Future of Health for People
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Attachment 1. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

MAY 26 2010

The Assigned 510(k) number is: K100942

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

   Correspondence:
   Nicky Pan
   Regulatory Affairs Specialist
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   Date of submission: April 02, 2010

2. Device name:
   Proprietary name: U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer

   Regulatory information:
   A. Regulation section: 21 CFR 880.2910
   B. Classification: Class II
   C. Product Code: FLL, Clinical electronic thermometer
   D. Panel: General Hospital (80)

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3. Intended Use:
   The U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer are intended for the intermittent measurement and monitoring of human body temperature from ear canal. The device is indicated for use by people of all ages in the home.

4. Device Description:
   The U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer are characterized by measuring human body temperature in the ear canal. It utilizes infrared technology to measure either infrared energy emitted from the eardrum and surrounding tissues when making a temperature measurement.

   Substantial Equivalence Information:

   A. Predicate device name:
   Fora ComfortScan Ear Thermometer, model TD-1261B

   B. Predicate K number: K081445

   C. Comparison with predicate:
   The modified U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer have the following similarities to the predicate device:

   - same operating principle,
   - same fundamental scientific technology,
   - incorporate the same basic circuit design,
   - incorporate the same materials,
   - same shelf life
   - packaged using the same materials, and
   - Manufactured by the same process.

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The modifications encompass:

- a modification in the user interface
- modification in the physical appearance
- labeling change due to the modifications
- Removed the data transmission function

5. Test Principle:
   The ear thermometer measures temperature by reading infrared radiation emitting from eardrum tissue. The small con-shape end of the thermometer is inserted into the ear canal, where the eardrum (tympanic membrane) and surrounding tissues give off heat. The thermometer converts it into a temperature value.

6. Performance Characteristics:
   U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer have the same performance characteristics as the predicate device.

   A comparison of system accuracy performance demonstrated that the U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer and the currently marketed Fora ComfortScan Ear Thermometer, TD-1261B (cleared under K081445) are substantially equivalent.

   Software verification and validation, performance and safety tests confirmed that the performance, safety and effectiveness of the U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer are equivalent to the predicate device.

7. Conclusion:
   Based on the information provided in this submission, the U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer are substantially equivalent to the predicate FORA ComfortScan Ear Thermometer, model TD-1261B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Nicky Pan
Specialist of Regulatory Affairs
Taidoc Technology Corporation
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Taipei County
China (Taiwan) 24888

MAY 2 6 2010

Re: K100942
Trade/Device Name: U-RIGHT TD-1115 Ear Thermometer and U-RIGHT TD-1118 Ear Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: April 27, 2010
Received: April 29, 2010

Dear Mr. Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8. Indications for Use

Indications for Use

510(k) Number:

Device Name: U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer

Indications for Use:

The U-RIGHT TD-1115 ear thermometer and U-RIGHT TD-1118 ear thermometer are intended for the intermittent measurement and monitoring of human body temperature from ear canal. The devices are indicated for use by people of all ages in the home.

Prescription Use _____ And/Or Over the Counter Use __X___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation (ODE)
510(k) K100942